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EXAMINER	
DICKINSON, PAUL W	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,164	NAGAHARA ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *3, 6, 13-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4,5,7-12 and 15-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/30/2006 and 10/3/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of the following in the reply filed on 12/6/2007 is acknowledged:

Regarding the first election requirement, Applicants elect lansoprazole, or an optically active isomer thereof or a salt thereof in claim 10 as a single species.

Regarding the second election requirement, Applicants elect a capsule whose main component is not a gelatin containing polyethylene glycol.

Regarding the third election requirement, Applicants elect a capsule whose component is a water-soluble polysaccharide.

Regarding the fourth election requirement, Applicants elect a capsule whose main component is pullulan.

Regarding the fifth election requirement, Applicants elect a capsule preparation which comprises at least two kinds of granules.

Regarding the sixth election requirement, Applicants elect a capsule preparation which comprises granules having a coating.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-24 are pending. In the reply filed on 12/6/2007, the Applicant stated that the claims readable on the elected species are Claims 1, 2, 4, 5, 7-12, 15, and 17-24 (see p 2). The Examiner finds, however, that Claim 16 also reads on the elected species, in addition to the above. Claims 3, 6, and 13-14 are directed to a nonelected species and are hereby withdrawn. Claims 1, 2, 4, 5, 7-12, and 15-24 are currently under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 and 21-23 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention.

The phrase "wherein the PPI is an optically active isomer (R-isomer) of lansoprazole" in Claim 12 is vague and indefinite. It is unclear if Applicant is claiming the R-isomer of lansoprazole only, or any optically active isomer (the S-isomer).

The phrase "wherein the controlled-release coating layer is a pH-dependent soluble controlled-release coating film" in Claim 21 is vague and indefinite. It is unclear what parameters or attributes of the film are pH-dependent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under

> the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 7-12, and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by US 20050181052 ('052). Instant Claims 1, 7-12 are directed to a capsule preparation comprising lansoprazole. '052 discloses a pharmaceutical composition comprising microtablets, wherein said microtablets comprise lansoprazole (a medicine unstable to moisture) and enclosed inside a capsule (see ¶ 1, 13, 61-63, Examples 1-2). The composition (a capsule preparation) taught by '052 is stable in a low moisture state (see ¶ 61-63). This argument is supported by the wet granulation step (see ¶ 67). The disintegration in acidic media of the capsules disclosed by '052 was evaluated at a pH of 1 and a pH of 6.8 (see ¶ 70; Table 1; pH of 1 calculated from pH=-log(0.1NHCl)). While the drug release profile is different for the two solutions, each capsule did disintegrate, releasing lansoprazole, at either pH level over 60 minutes, and this qualitative property (that the capsule disintegrated at both pHs to release lansoprazole) is reasonably considered a pH-independent disintegration property.

Instant Claim 2 is directed to a capsule preparation stable in a low moisture state which is less or equal to relatively humidity of 35%. '052 does not explicitly teach this property. The material elements of Instant Claim 2 are, however, fully anticipated by the disclosure of '052. Appreciation of the capsule's moisture stability at a certain humidity level is not, in itself, patentable subject matter. Where the claimed and prior art products are identical or substantially

identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01, I.

Instant Claim 12 is directed to a capsule preparation wherein the PPI is an optically active isomer (R-isomer) of lansoprazole. The capsules disclosed by '052 are a racemic mixture comprising both the R- and S- isomers of lansoprazole (see ¶ 12). Instant Claim 12 uses open terminology, and does not exclude the presence of more than one optically active isomer (or other components). The racemic mixture disclosed by '052 therefore anticipates the instant claim.

Instant Claim 15 is directed to a capsule preparation wherein the content in the capsule is fine granules optionally coated, granules optionally coated and/or tablets optionally coated. The capsules disclosed by '052 contain granules coated with an enteric coating (see ¶ 61; Examples 1-2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to

> be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4 and 16-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 20050181052. Instant Claim 4 is directed to a capsule preparation comprising a water-soluble polysaccharide as the main component. As stated above, '052 discloses a pharmaceutical composition (a capsule preparation) comprising microtablets, wherein said microtablets comprise

lansoprazole (a medicine unstable to moisture) and enclosed inside a capsule. The capsule preparation taught by '052 suggests that the disclosed capsules are stable in a low moisture state and have pH-independent disintegration properties. The capsule preparation disclosed by '052 further comprises a lubricant, optionally one or more excipients, and an enteric coating, wherein the weight ratio of lansoprazole to lubricant is from about 1:4 to about 8:1, respectively (see ¶ 1). Preferred, not-limiting, examples of excipients include microcrystalline cellulose, maltodextrin, starch, and various cellulose derivatives (see ¶ 26, 57, 60). All of the above excipients are polysaccharides. '052 fails to teach an example wherein the disclosed polysaccharides are the main component. Optimization of this parameter is not, in itself, patentable subject matter. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 CCPA 1955). MPEP 2144.05, II. One of ordinary skill in the art would therefore be motivated to select a polysaccharide for incorporation into the capsule preparation disclosed by '052 and optimize relative concentrations of the components to afford the instant invention.

Instant Claim 16 is directed to a capsule preparation which contains at least two solid preparations selected from fine granules, granules and tablets in combination. Instant Claim 17 is directed to a capsule preparation wherein the

combined solid preparations have different medicine release properties. Instant Claim 18 is directed to a capsule preparation wherein the solid preparations have a coating layer. '052 discloses two different microtablet formulations, one dried and one undried, both having a coating (see Examples 1-2; Table 1). '052 further discloses that both of these microtablet formulations release lansoprazole, but at different rates (different medicine release properties). Both formulations have the same function (release lansoprazole) and one of ordinary skill in the art would be motivated to use both in combination with each other, affording the instant invention. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See MPEP 2144.06, I.

Instant Claims 19-24 are directed to limitations of the coating layer in Instant Claim 18. Instant Claim 19 is directed to an enteric coating layer. The capsule preparation disclosed by '052 have an enteric coating layer (see ¶ 61-63; Examples 1-2). Instant Claims 20 and 24 are directed to a controlled-release coating layer. The coating layer taught by '052 is reasonably interpreted as a controlled-release coating. Instant Claim 21 is directed to a coating layer that is a pH-dependent soluble controlled-release coating film containing a polymer soluble within a range of pH 6.0 to pH 7.5. '052 discloses specific polymers to be incorporated into the enteric coating, including preferred polymers that are water

soluble at a pH of 6.5, such as polyvinyl pyrrolidone (see '052, ¶ 19; US 7288174, col 7, ln 4-15). Furthermore, the coating layer taught by '052 is reasonably interpreted as a controlled-release coating layer that is a diffusion-control type controlled-release film (Instant Claim 22) and a time release type controlled-release coating film (Instant Claim 23) (see '052, Examples 1-2). These attributes are supported by the release profile disclosed for the capsule preparation (see Table 1). One of ordinary skill in the art would therefore be motivated to select polymeric components that provide an enteric coating (Instant Claim 19), a controlled-release coating layer (Instant Claims 20 and 24), a controlled-release coating layer that is a pH-dependent soluble controlled-release coating film containing a polymer soluble within a range of pH 6.0 to pH 7.5 (Instant Claim 21), wherein the latter coating layer is a diffusion-control type controlled-release film (Instant Claim 22) and a time release type controlled-release coating film (Instant Claim 23).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 20050181052 in view of 5665348. Instant Claim 5 is directed to a capsule preparation comprising pullulan as the main component. '052 discloses a pharmaceutical composition comprising microtablets, wherein said microtablets comprise lansoprazole (a medicine unstable to moisture) and enclosed inside a capsule. The capsule preparation taught by '052 suggests that the disclosed capsules are stable in a low moisture state and have pH-independent disintegration properties. As stated above, preferred, not-limiting, examples of

excipients taught by '052 for incorporation into the disclosed capsule preparation include microcrystalline cellulose. '052 fails to disclose a capsule preparation comprising pullulan as the main component.

'348 discloses that microcrystalline cellulose and pullulan are both known in the art as functionally equivalents used as excipients in solid preparations (see col 3-4, bridging paragraph).

One of ordinary skill in the art would be motivated to combine the disclosures of '052 and '348 to afford the instant invention, with a reasonable expectation of success. Specifically, owing to their precedent as functional equivalents in the art, one would be motivated to substitute pullulan for microcrystalline cellulose in the composition disclosed by '052. One would further be motivated to optimize the relative concentrations of the composition components, affording the instant invention. See MPEP 2144.05, II.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 8:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Dickinson
Examiner
AU 4173

January 28, 2008

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER